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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/804,592	03/19/2004	William Galbraith	80154	9558
26253	7590	11/01/2005	EXAMINER	
DAVID W. HIGGET, VP AND CHIEF IP COUNSEL BECTON, DICKINSON AND COMPANY 1 BECTON DRIVE, MC 110 FRANKLIN LAKES, NJ 07417-1880			YU, MELANIE J	
		ART UNIT	PAPER NUMBER	
		1641		

DATE MAILED: 11/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/804,592	GALBRAITH, WILLIAM	
	Examiner	Art Unit	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### **Status**

1) Responsive to communication(s) filed on 17 August 2005.

2a) This action is FINAL.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### **Disposition of Claims**

4) Claim(s) 1-6 and 24-31 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-6 and 24-31 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### **Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 19 March 2004 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### **Priority under 35 U.S.C. § 119**

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### **Attachment(s)**

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_

4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_

5) Notice of Informal Patent Application (PTO-152)

6) Other: \_\_\_\_\_

## **DETAILED ACTION**

1. Applicant's amendment filed 17 August 2005 has been entered. Claims 1-6 and 24-31 are currently pending in this application. Claims 30 and 31 have been identified as original claims, it is noted that these claims are actually currently amended.

### ***Withdrawn Rejections***

2. Previous rejections under 35 USC 112, second paragraph have been withdrawn. Double patenting rejections of claims 2-5 have been withdrawn in light of applicant's amendment.

### ***Claim Rejections - 35 USC § 102***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 1-6 and 24-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Sundrehagen (US 5,919,708).

Sundrehagen teaches an apparatus comprising an insoluble support (a solid support of beads of cross-linked agarose are insoluble; col. 11, lines 46-49) having a ligand of bromosulfophthalein attached thereto (signal forming agent that binds to albumin and is therefore a ligand for albumin, col. 7, line 66-col. 8, line 6; col. 8, lines 61-63; albumin and signal forming agent bind to solid support for detection, col. 11, lines 46-65; col. 12, lines 10-14; col. 12, line 63-col. 13, line 4, and therefore ligand of bromosulfophthalein is attached to solid support), wherein the insoluble support is contained or supported in a container of columns (separation is obtained by filtering through a filter comprising a filter surface, wherein the filter surface is an insoluble support and the filter is a container, col. 11, lines 19-25). Sundrehagen further teaches

the filter container being a filter plate (col. 11, lines 21-25) and the insoluble support being a matrix (col. 11, lines 47-48).

*Claim Rejections - 35 USC § 103*

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 24 and 27-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pieper et al. (US 2002/0127739) in view of Sundrehagen (US 5,919,708).

Pieper et al. teach a column comprising one or more additional supports capable of binding one or more non-albumin proteins (par. 0067), wherein the supports include one or more supports capable of binding IgA and IgG (different matrices carrying different binding agents to remove proteins from a sample is provided at par. 0067; sample proteins of IgG and IgA are non-albumin and are listed at pg. 9, Table 1). Pieper et al. fail to teach a ligand of bromosulfophthalein.

Sundrehagen teaches a ligand of bromosulfophthalein attached to an insoluble support (col. 7, line 66-col. 8, line 6; col. 11, lines 46-65) of a filter plate (col. 11, lines 21-25), in order to detect albumin bound to a support.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the column of Pieper et al., a binding agent of bromosulfophthalein as taught by Sundrehagen, in order to provide a detectable ligand specific to albumin, which strongly influences the affinity of albumin to the ligand and provides detectable properties upon binding which ensures removal.

Regarding claims 30 and 31, Pieper et al. teach a support bindable to IgA (proteins for which a multi-component antibody affinity matrix are listed at pg. 9, Table 1; IgA has a separate column body par. 0102) and a support bindable to IgG (proteins for which a multi-component antibody affinity matrix are listed at pg. 9, Table 1; IgG has a separate column body par. 0102) wherein the support comprises protein A and G cartridge (a column comprising protein G and A bind IgG; see under Table 1).

### ***Double Patenting***

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-6 and 24-31 provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-6 and 24-31 of copending Application No. 10/922,560. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

### ***Response to Arguments***

3. Applicant's arguments filed 18 August 2005 have been fully considered but they are not persuasive. Applicant correctly argues that Sundrehagen does not teach a ligand of bromosulfophthalein at column 11, lines 49-54. However, the albumin bound to the solid support is bound to a signal forming agent (col. 11, lines 46-65; col. 12, lines 10-14; col. 12, line 63-col. 13, line 4) of bromosulfophthalein, which is taught at column 7, line 66-column 8, line 6.

Therefore the signal forming agent of bromosulfophthalein is bound to a solid support in Sundrehagen. For these reasons Sundrehagen does overcome the deficiencies of Pieper.

4. With respect to applicant's amendment regarding the double patenting rejection of claims 1-6 and 24-31, claims 1-6 and 24-31 have not been cancelled from co-pending application 10/922,560. Until these claims have been cancelled, the provisional double patenting rejection is proper.

*Conclusion*

5. No claims are allowed.
6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Yu whose telephone number is (571) 272-2933. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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6/28/05